UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,884	04/14/2004	Grant Reynolds	1025-US1	9074

35159 7590 10/05/2005

TARO PHARMACEUTICALS
5 SKYLINE DRIVE
HAWTHORNE, NY 10532

EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,884	REYNOLDS, GRANT	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JDD

DETAILED ACTION

Receipt is acknowledged of the applicant's Oath or Declaration filed on 12/30/2003.

Receipt is also acknowledged of the applicant's Information Disclosure Statement filed on 11/12/2003.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-21, drawn to a method of making a skin softening ointment, classified in class 424, subclass 69.

   II. Claims 21-23, drawn to a method of making a skin softening ointment comprising glycerol, PEG-8, white petrolatum, and salicylic acid, classified in class424, subclass 69.

   III. Claim 24, drawn to a skin softener composition, classified in class 424, subclass 400+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II and Invention III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made

via materially different processes. The product as claimed can be made without the vacuum, heating, and cooling steps as set forth in Inventions I and II.

3. Inventions I and II are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions I and II comprise different ingredients and method steps. As such, the methods of Inventions I and II have different scopes and a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

4. Searching the inventions of Groups I – III together would impose a search burden on the examiner. In the instant case, the search of two distinct methods and a composition would impose a search burden.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – IV are not required for one another, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. During a telephone conversation with Donna Robertson-Chow on 8/12/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,976,555 ('555).

'555 teach skin care compositions and methods of making said compositions (abstract). Like the instant claim set, the skin care compositions advanced by '555 can comprise the following: (1) a humectant, such as glycerol or propylene glycol (column 8, lines 61-64 and Example 7); (2) a non-aqueous thickener, such as hydroxyethyl cellulose (column 9, lines 34-42); (3) urea (Example 7); (4) a non-aqueous base, such as lanolin (column 7, lines 39-56); (5) an emulsifier, such as cetyl alcohol; and (6) salicylic acid, a well-known preservative (column 8, line 65 – column 9, line 2).

Like the instant application, the skin care compositions advanced by '555 can be made through a series of heating, mixing, vacuum, and cooling steps (column 15, line 44 – column 16, line 5 and column 11, line 55 – column 12, line 4). According to '555, these mixing and blending procedures are well known in the art (column 11, lines 55-56).

Although '555 teach methods of preparing a skin care agent comprising heating, mixing, vacuuming, and cooling the above mixture 1-6, '555 is deficient in the sense that it does not teach the exact mixing, heating, cooling and vacuuming steps as set forth in the instant Claim 1. However, based on particular application and the intended use of the composition, one of ordinary in the art would have been able to modify the heating, cooling, mixing, and vacuuming steps of the method based on the particular application. Based on the teachings of '555, there is a reasonable expectation that mixing, heating, cooling, and vacuuming the above mixture 1-6 would result in an effective skin care composition. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the heating, cooling, mixing, and vacuuming steps based on the teachings of '555.

Claims 7-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,387,382, US 6,150,403, and US 6,214,318 are cited as patents of interest in their disclosures of methods of preparing skin care compositions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

9/30/05

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500